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FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			WEISS JR, JOSEPH FRANCIS	
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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

Paper No. 23

Application Number: 09/051443

Filing Date: 10 April 1998

Appellant(s): Carl Widerstrom

**MAILED**  
**DEC 19 2003**  
**GROUP 3700**

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Mr. William E. Booth

For Appellant

EXAMINER'S ANSWER

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This is in response to the appeal brief filed 6 October 2003.

**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is deficient because it presents an argument as to what a single use inhaler is and gives a claim by claim breakdown and not a general summary of the invention.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

Appellant's brief includes a statement that claims 1-5, 7-8; 9; 10-12 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

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**(8) ClaimsAppealed**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) Prior Art of Record**

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5743250	Gonda	04-1998
5881719	Gottenauer et al.	03-1999
5533505	Kallstrand et al.	07-1996
4400084 DE	Goettenauer et al.	07-1995

**(10) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

***Claim Rejections - 35 USC § 103***

1. Claims 1-5 & 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goettenauer et al (DE 4400084 A1) in view of Gonda (US 5743250).

In regards to claim 1, Goettenauer discloses an inhaler (33) comprising an inhalation channel (21); a first container (1) for containing medicament; a first release means (3/28) to release medicament into the channel; a subsidiary container (1) for containing medicament; a subsidiary release means (3/28) to release the subsidiary container's medicament into the inhalation channel; wherein the two release means are independently operable which results in one or more of each containers being operated to release medicament into the channel at the same time to vary dosage and which is fully capable of having different fractions or relative ratios of medicament contained within the different medicament containers to include where the subsidiary container which may contain a dose that is a predetermined fraction that is less than that of the first

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dose, but does not explicitly disclose such. However, Gonda disclose such (note the abstract which discloses repeated deliveries of medicament until the desired result is achieved, note that the containers/blisters may have different amounts of medicament (col. 42 lines 6-50) these differences being predetermined when the blisters are filled, note the abstract for the use of a dry powder). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Gonda and used them with the device of Goettenauer. The suggestion/motivation for doing so would have been to provide for a more customized dosing regime that would compensate for the losses of medicament that accompany inspiratory delivery, col. 4 lines 25-30. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 2, Goettenauer discloses the containers as being integral with the inhaler.

In regards to claim 3, Goettenauer discloses the containers as being depressions in at least one wall of the inhalation channel with the release means comprising films that seal the depressions.

In regards to claim 5, Gottenauer & Gonda disclose the medicament used as being in a powdered form.

In regards to claim 7, Gottenauer discloses the inhaler as having at least 2 subsidiary containers which are fully capable of containing at least 2 subsidiary doses which are a predetermined fraction of a first

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dose in a first container which may contain a dose that is a predetermined fraction that is less than that of the first dose.

In regards to claim 8, the suggested device discloses subsidiary doses with different fractions of a first dose which may contain a dose that can be a predetermined fraction that is less than that of the first dose. (See Gonda Col. 42 lines 6-50 & note the operation of Gonda regarding partial blister contents delivery).

In regards to claim 4, the suggested device discloses the release means as comprising one or more elongated members (See Goettenauer Fig 8) attached to or integral with said films (by dint of container film 36 which is integral with cover film 3) and with free ends which may be pushed by a user in order to remove the films from their respective depressions, thereby releasing medicament contained within the respective depressions, but Appellant arranges its release means to a user my pull instead of push, i.e. a reversal of known parts for a known purpose.

It is noted that Appellant's specification does not set forth this reversal of parts, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than to constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

2. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottenauer et al (5881719) in view of Gonda (US 5743250).

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In regards to claim 9, Gottenauer discloses the a method of providing a variable dose in a single inhaler that provides an inhalation channel (7) through which a user may inhale. A first container (31) for containing a first dose (38) and a first release means (9) for releasing a first dose said method further comprising providing at least one subsidiary container (any of the other blisters 31), containing a subsidiary dose (the dose withing any of the other containers 31) which provides an independently operable subsidiary release means (any other of levers 9) arrangement for releasing the subsidiary dose into the inhalation channel such that one or both of said first dose and said subsidiary dose may be released into said inhalation channel at the same time and such that a variable dose may be provided, but does not explicitly disclose the subsidiary dose being a predetermined fraction that is different from the first dose. However, Gonda disclose the use of predetermined fractions of doses of one blister relative to another for use in medicament delivery devices wherein some of the doses are a lesser fraction of medicament relative to a greater dose contained in another blister and via the blood glucose monitoring permits the user to determine if the need exists to repeat the dosing and/or include subsidiary doses. (note the abstract which discloses repeated deliveries of medicament until the desired result is achieved, note that the containers/blisters may have different amounts of medicament (col. 42 lines 6-50) these differences being predetermined when the blisters are filled, note the abstract for the use of a dry powder). The references are analogous since they are from the same field of endeavor, the medicament delivery arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Gonda and used them with the device of Gottenauer. The suggestion/motivation for doing so would have been to more accurately tailor the amount of drug delivered to a user for modulating the physiological parameter appropriately. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

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In regards to claim 10, Gottenauer discloses the a method of providing a variable quantity of a substance in a channel for an administration device comprising the steps of opening a first container (31) containing a first dose (38) of a substance and dispensing the substance in the channel and selectively opening a subsidiary container (any of the other blisters 31), containing a subsidiary dose (the dose within any of the other containers 31) and representing a total quantity of substance required and dispensing the substance in into the channel, but does not explicitly disclose the subsidiary dose being a predetermined fraction that is different from the first dose which is less than the first dose. However, Gonda disclose the use of predetermined fractions of doses of one blister relative to another for use in solid medicament delivery devices wherein some of the doses are a lesser fraction of medicament relative to a greater dose contained in another blister. The references are analogous since they are from the same field of endeavor, the medicament delivery arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Gonda and used them with the device of Gottenauer. The suggestion/motivation for doing so would have been to more accurately tailor the amount of drug delivered to a user for modulating the physiological parameter appropriately. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

In regards to claim 11, the suggested device discloses that the substance is medicament.

In regards to claim 12, the suggested device discloses the administration device as an inhaler.

***Double Patenting***

3. Claims 1-5 & 7-8 are rejected under the judicially created doctrine of obviousness-type double patenting (Common Assignee) as being unpatentable over claims 1-19 of U.S. Patent No. 5533505 in view of Gonda. Although the conflicting claims are not identical, they are not patentably distinct from each other

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because both set forth an inhaler having an inhalation channel with a container formed a depression in a wall of the inhaler that is integral with the container for containing a dose of medicament with a film release means that is pulled by a user for the release of medicament, however the claims of the instant application set forth the use of multiple containers, whereas US 5533505 discloses the use of only one such container, i.e. the duplication of a known part for a known purpose, but Gonda discloses such. (note the abstract which discloses repeated deliveries of medicament until the desired result is achieved, note that the containers/blisters may have different amounts of medicament (col. 42 lines 6-50) these differences being predetermined when the blisters are filled, note the abstract for the use of a dry powder). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Gonda and used them with the device of Goettenauer. The suggestion/motivation for doing so would have been to provide for a more customized dosing regime that would compensate for the losses of medicament that accompany inspiratory delivery, col. 4 lines 25-30. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, it is noted that Appellant's specification does not set forth the duplication of a known part for known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, **barring a convincing showing of evidence to the contrary**. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice

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of design, rather than to constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary.

**(11) Response to Argument**

All the arguments presented by Appellant are presented on two grounds:

1-That none of the prior art references set forth a “Single use inhaler” that he presents in his pre-amble to attempt to set forth a scope different from the prior art and that the Reference Gonda does not teach the use of varying amounts of medicament in different dose containers used by an inhaler.

Response to “Single use inhaler” as distinguishing arguments.

The phrase has no support in the prior art as a unique species of inhaler. The USPTO maintains no specific sub-class in the respiratory arts for “Single use inhalers.” Appellant’s use of the phrase in the pre-amble does not set forth a distinguishing scope from the prior art that sets forth inhalers that may be used more than once. No unique structure is presented that makes Appellant’s inhaler “single use.” In fact tabs 22 & 24 of Appellant’s currently disclosed invention are independently acutable and thus a user can open one dose and use the device and then later open the other dose and use it a second time. Inhalers that have multiple doses built into them can be used once and thrown away. Thus despite the manner that Appellant uses the language “Single use inhaler” in the pre-amble, the language does not give life, meaning or vitality to the claim, but merely sets forth a non-limiting intended manner of use the inventor “Hopes” the end user will honor or perform. There is no structure to permit a one time use of the device and then lock out the device from any further use. Hence all the references used in the rejections was relevant prior art eligible for use in the rejection to all the claims.

Response to the issue of Gonda’s teaching varying the amount of medicament in dose containers

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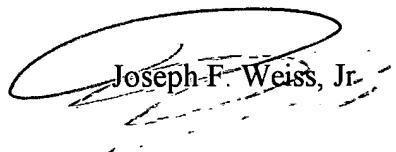
Appellant's brief is correct in terms of citing the relevant portion of the teaching that discloses the use of different amount of medicament in different containers of a single unitary strip of containers. (Col. 42, lines 6- 50) Appellant's asserts that it does not teach varying the amounts of medicament in different containers of a single strip, but that it teaches the use of different strips of containers, where the amounts in the medicament between the strips and not between the containers of a single strip. Appellant's interpretation of this passage is in error. The passage never mentions different strips, just different containers. The passage in col. 42 lines 26-28 is the most relevant. The indices can also provide information on "the amount of insulin dispensed from each container which might be particularly useful if the containers included different amounts of insulin." The reason why the examiner can reach the conclusion that Gonda means different containers within the same strip is due to the fact that Gonda uses the term "container" throughout his teaching to mean element 1 of his invention as depicted in the drawings. Col. 16 line 63 to col. 19 line 37 is Gonda's description of what is element 1, a single drug container that is part of a greater strip. The top of col. 18 lines 1-5 is most instructive on this point.

"The device 40 is loaded and operates with a plurality of interconnected disposable containers 1 which form a package 46." (See also figure 7) Thus in light of what Gonda defines as a container, the strips that are then formed from the containers, and Gonda's usage of container language in col. 42 lines 6-50, there is a reasoned basis to conclude that Gonda's reference in col. 42 lines 26-28 means that he assembles a single strip 46 made up of containers 1, having varying amounts of medicament contained within them relative to each other and thus finds it necessary to teach the use of indices on these containers so the patient knows what dose of medicament they are receiving.

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Appellant arguments for all the rejections are all solely based upon these two issues. Appellant has raised no other additional arguments for any of the rejections present. For the above reasons, it is believed that the rejections should be sustained. The issue of preamble "single use inhaler" scope has been found to not provide a meaningful structural limitation, appellant's device itself not structurally meet such a scope limitation and the prior art references used are fully capable of only being used once. On the issue of providing varying amounts of medicament in containers common to the same dose strip a reading of the reference in its entirety and by what it means by "container" leads to the reasoned conclusion that medicament dose is varied in containers of a common strip, hence appellant is in error in his position on these two issues raised on appeal.

Respectfully submitted,



Joseph F. Weiss, Jr.

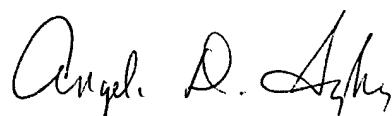
December 4, 2003

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